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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR <sub>S</sub>	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,219	11/19/2001	Brian J. Stockman	6283NCP2	9179

26813      7590      01/28/2003

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EXAMINER

BAKER, MAURIE GARCIA


ART UNIT      PAPER NUMBER

1639

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. <b>10/044,219</b>	Applicant(s) <b>Stockman et al</b>	
Examiner <b>Maurie G. Bak r, Ph.D.</b>	Art Unit <b>1639</b>	

-- Th MAILING DATE of this communication app ars on the cov r sh et with the correspondenc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_
- 2a)  This action is FINAL.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 1-46 is/are pending in the applica
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from considera
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-46 are subject to restriction and/or election requirem

## Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1)  Notice of References Cited (PTO-892)                      4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5)  Notice of Informal Patent Application (PTO-152)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6)  Other:

## DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1639 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5, drawn to a method of creating a chemical compound library, classified in various classes depending on the compounds of the library, for example, any of class 540-570, subclasses various and/or class 435, subclasses 7.1, 7.2 or DIG 46-51.
  - II. Claims 6-10, drawn to a chemical compound library, classified in various classes depending on the compounds of the library, for example, any of class 540-570, subclasses various and/or class 435, subclasses 7.1, 7.2 or DIG 22-39.
  - III. Claims 11-17, drawn to a method of identifying a lead chemical template, classified in various classes depending on the method of identifying, for example, class 435, subclasses 7.1, 7.2, 7.4-7.95 or class 436, subclasses 501-505, 43+.
  - IV. Claims 18-30, drawn to a method of identifying a compound that binds to a target molecule, classified in class 436, subclass 173.
  - V. Claims 31-45, drawn to a *second* method of identifying a compound that binds to a target molecule, classified in class 436, subclass 173.
  - VI. Claim 46, drawn to a method of identifying a protein function, classified in class 435, subclass 7.1.
2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the library of Group II could be made by a different process than the method of Group I. For example, the library could be chemically synthesized by solid phase techniques.

4. Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the library of Group II could be used as a starting material for further library synthesis.

5. Groups I and III are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the method of making the library (Group I) is different from the method of use of the library (Group III), requiring different steps and having completely different end results. The method of Group I only has steps of selecting compounds, while the method of Group III has additional steps of

identifying and then using that which is identified. Moreover, the end result of the method of Group I is a library, while the end result of the method of Group III is a “lead chemical template”.

6. Groups IV – VI are not related to Groups I – III. The inventions are not disclosed as capable of use together for the following reasons. In the instant case, Groups I – III deal with a chemical compound library, and methods of making and using such a library (see paragraphs 3-5 above). The methods of Groups IV – VI do not deal with libraries but instead recite “mixtures of test compounds”.

7. However, if applicant were to argue that the “mixtures of test compounds” recited in the claims of Groups IV – VI is the same as the “chemical compound library”, then the following is noted (i.e. paragraphs 8 and 9).

8. If “mixtures of test compounds” is the same as the “chemical compound library”, then Groups II and IV – VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the library of Group II could be used as a starting material for further library synthesis.

9. Furthermore, Groups I and III – VI are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, Group I is a method of making a library, while Groups III – VI are methods of use of a library. See paragraph 5 above. Additionally, the four methods of use (Groups III – VI) are different from each other because they have different steps and/or end results. Group III is different from Groups IV – VI because it is a method for identifying a “lead chemical template” (end result) and has a step of using the ligand to identify the template, which is not required by any of Groups IV – VI. Groups IV and V are different from each other because they use different NMR techniques. These NMR techniques require different steps and are considered to be different methodology (e.g. see instant specification, page 13, lines 11-13) representing patentably distinct subject matter. Group VI is different from either of Groups VI and V because the method of Group VI has a different end result (i.e. identifying protein function) and requires different steps.

10. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Please note that even though some of these groups could be classified in the same class/subclass, this has no effect on the non-patent literature search. Different methods and products would require completely different searches in these databases, and there is no expectation that the

searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

11. This application contains claims directed to patentably distinct species of the claimed invention for **Groups III – V**. Election is required as follows.

12. If applicant elects the invention of *any of Groups III-V*, applicant is required to elect from the following patentably distinct species.

Species of target molecule

*A specific* target molecule used in the method should be elected, for purposes of search.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and *a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim



remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

19. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306- 3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.  
January 23, 2003



MAURIE GARCIA BAKER, Ph.D.  
PATENT EXAMINER